July 9, 2009

Dr. Barbara Shane
Executive Secretary
National Toxicology Program (NTP) Board of Scientific Counselors
National Institute of Environmental Health Sciences (NIEHS)
P.O. Box 12233
MD A3-07
Research Triangle Park, NC 27709

Re: Comments on the Chemical Information Review Document for Deoxynivalenol (CAS No. 51481-10-8)

Dear Dr. Shane:

The North American Millers' Association (NAMA) and the American Bakers Association (ABA) appreciate the opportunity to submit these comments on the nomination of deoxynivalenol (DON) for toxicological evaluation by NTP/NIEHS.[1] NTP/NIEHS nominated DON for evaluation of chronic toxicity and carcinogenicity studies and reproductive toxicity studies.

The North American Millers' Association is the trade association representing the wheat, corn, oat and rye milling industry. NAMA's 47 member companies operate 170 mills in 38 states and Canada. Their aggregate production of more than 160 million pounds per day is approximately 95 percent of the total industry capacity. The ABA represents the interests of bakers before the U.S. Congress, federal agencies, state legislatures and international regulatory authorities. The ABA advocates on behalf of over 250 companies, both baking companies and their suppliers, including companies located in California. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious baked products for America's families. The baking industry generates over $70 billion in economic activity annually and employs close to half a million highly skilled people.

[1] 74 FR 25241 [May 27, 2009], http://edocket.access.gpo.gov/2009/pdf/E9-12204.pdf

We believe that NTP's resources would be better directed to studying chemicals that are not presently being adequately addressed, and request that NTP give DON a very low priority for testing, for the following reasons.

- The potential public health impacts of DON and other *Fusarium* toxins have been recognized for many years. Accordingly, these naturally-occurring compounds are the focus of ongoing regulatory and risk management attention globally.
- DON is the most extensively studied tricothecene. Abundant data exist, and based on review and expert evaluation by worldwide food regulatory and scientific bodies, have been determined to be sufficient for tolerable daily intake levels and regulatory and/or guidance to be established.
- Government researchers, grain producers and handlers, the milling industry and food processors are actively engaged in monitoring, management practices and research to control exposures from contaminated grains.

Potential exposures to DON in the US and Europe are episodic and relatively infrequent, as outbreaks are associated with climatic factors. Nevertheless, levels of DON are regulated. FDA maintains advisory levels of 1 ppm in finished wheat products for human consumption, as well as limits for grain and byproducts used in poultry, swine and cattle feed.[2]

The North American Millers' Association (NAMA) and the American Bakers Association ABA) support the comments submitted by the Grocery Manufacturers Association (GMA) to the docket. Furthermore, NAMA is actively involved in US government research initiatives related to fusarium head blight and DON. The US government, through the US Department of Agriculture and the US Wheat and Barley Scab Initiative, has spent many years on the development of more resistant wheat and barley varieties and the creation and dissemination of information on crop management techniques to reduce the incidence and severity of fusarium head blight and DON. It is our opinion that further emphasis on controlling fusarium head blight and DON accumulation at the US Department of Agriculture is the most important use of government resources at this time.

Sincerely,

[Redacted] [Redacted]

Jane B. DeMarchi
Director of Government Relations
North American Millers' Association

Rasma I. Zvaners
Senior Manager, Government Relations
American Bakers Association

[2] http://www.gipsa.usda.gov/GIPSA/documents/GIPSA_Documents/b-vomitox.pdf